Remarks

The Office Action mailed September 10, 2002 has been received and reviewed. Claims 1, 6-9, and 11-15 having been amended, the pending claims are claims 1-15. Reconsideration and withdrawal of the rejections are respectfully requested.

The claims have been amended to clarify the claimed invention. Claim amendments have not been made to narrow the claimed invention and no new matter is added by the claim amendments. Support for claims amendments is found throughout the specification. For example, support for the recitation "neuronal" in claims 1, 6-9, and 11-15 is found in the recitation "neuron-like" in Table I, p. 18. Support for the recitation "wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34" in amended claims 1, 9, 14, and 15 is found at p. 9, line 15 and p. 9, line 32 through p. 10, line 4 of the specification. And support for the recitation "wherein the nonfunction is the result of neurodegeneration" in amended claims 14 and 15 is found on p. 1, line 27 of the specification.

Traverse of Restriction Requirement

In response to the Restriction Requirement mailed June 18, 2002, Applicants elected, with traverse, Group 37 (claims 1-15), in part drawn to methods of contacting cells *in vivo* with SEQ ID NO:2 (Response to Restriction Requirement, filed July 17, 2002). Applicants continue to traverse this Restriction Requirement. Applicants submit that the restriction requirement, limiting Applicant to contacting cells *in vivo* with only one of SEQ ID NO:1-35, places an undue burden on the Applicants by requiring payment of 69 separate filing fees for examination of the nonelected claims, as well as the added costs associated with prosecuting 70 applications and maintaining 70 patents.

Applicants repeat the request that the Examiner regroup at least Group 70 (claim 1-15), in part drawn to methods of contacting cells *in vivo* with a specific combination of peptides, to the extent that such combinations include SEQ ID NO:2.

Further, Applicants repeat their argument that claims 1-6, 9-11, 14, and 15 are linking claims. Accordingly, the Examiner's restriction appears to be more appropriately an election of species with respect to specific sequences and with respect to *in vivo* and *in vitro* methods. See MPEP § 809.02. Thus, Applicants traverse on the grounds that the generic (linking) claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the Examiner. Applicants again request rejoinder and that the requirement be withdrawn upon the finding of an allowable genus.

In maintaining the restriction requirement, the Examiner argued that "the claims recite open language" and therefore, "the claims embrace methods wherein cells are contacted with generic compositions comprising SEQ ID NO:2" (p. 2 of Office Action mailed September 10, 2002). It is unclear how this statement supports the Examiner's position that claims 1-6, 9-11, 14, and 15 are not generic linking claims. Clarification is requested. The Examiner also argued "that [c]laim 1 is not a linking claims, since the generic 'constituent peptide thereof' does not accurately reflect the Markush group recited in claim 1" (p. 2 of Office Action mailed September 10, 2002). Again, the Examiner is requested to clarify this statement. A review of the MPEP (see MPEP § 806.04(a) to § 806.04(i)) reveals no requirement that a species is defined only by its inclusion within a Markush group in a generic claim. Rather, species "are always the specifically different embodiments" and a claim that includes "two or more of the disclosed embodiments" is "designated a generic or genus claim" (see MPEP § 806.04(e)).

Finally, in paragraph 17 of the Office Action mailed September 10, 2002, the Examiner rejected claims 14 and 15 as being anticipated by the disclosure of the administration of "colostrinin or an analog thereof" in Janusz et al. (WO 98/14473). This rejection includes no mention of SEQ ID NO:2. Thus, at least for claims 14 and 15, it appears that the Examiner has

examined the generic claim. Applicants again request rejoinder and that the requirement be withdrawn upon the finding of an allowable genus.

Examiner Interview

An Examiner's Interview was held on October 15, 2002 between the Applicants' Representative and Examiners Nichols and Kemmerer. The claim rejections of record were discussed. Examiner Nichols and Kemmerer are thanked for the courtesy of this interview.

Information Disclosure Statements

A copy of PTO-1449 mailed July 23, 2001 was considered and initialed by the Examiner on July 23, 2001, and a copy included with the Office Action. However, the PTO-1449 mailed June 12, 2001 has not been considered and initialed by the Examiner. As a courtesy, a copy of the PTO-1449 mailed June 12, 2001 is included with this communication as Exhibit A, for consideration by the Examiner.

Title

As the Examiner has suggested, the title of the invention has been amended to "USE OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF, TO PROMOTE NEURONAL CELL DIFFERENTIATION."

The Specification

As required by the Examiner, the specification has been amended to remove the embedded hyperlink on p. 9, line 27.

The Examiner objected to the specification for the following informalities: the misspelling of "nueral" on p.3, line 9; the misspelling of "terminii" on p.8, line 18; and a missing comma between "hydrophobicity and hydrophilicity" on p.8, line 24. The specification

has been amended to correct these errors. Withdrawal of the objection to the specification is respectfully requested.

Objections to the Claims

The Examiner objected to claims 1-15 for the recitation of non-elected inventions. Applicants respectfully traverse this objection. As discussed in the traverse of the restriction requirement, above, claims 1-6, 9-11, 14, and 15 are generic claims, and need not be restricted to the elected SEQ ID NO:2. Withdrawal of this objection to the claims is respectfully requested.

The 35 U.S.C. §112, First Paragraph, Rejection of claims 1-13

The Examiner rejected claims 1-13 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The Examiner alleged that "the specification, while being enabling for methods of promoting neuronal cell differentiation comprising contacting PC12 cells with the peptide of SEQ ID NO:2 or an active analog thereof which is full-length colostrinin, does not reasonably provide enablement for the claimed methods wherein any pluripotent neural cell is differentiated or analogs other than full-length colostrinin is administered to cells" (p. 4 of the Office Action mailed September 10, 2002). This rejection is respectfully traversed.

Specifically, the Examiner alleged that as the specification discloses colostrinin-induced differentiation for only a single cell line, the PC12 cell line, it would require undue experimentation of one of skill in the art to practice the invention commensurate with the broad range of cells encompassed by the claim. Applicants respectfully disagree. As noted by Vaudry et al. "Signaling Pathways for PC12 Cell Differentiation: Making the Right Connections," *Science* 296:1648-1649 (May 31, 2002), the PC12 cell line is art recognized as a model system for the study of neuronal differentiation (see, for example, the first and last paragraphs of Vaudry

et al.). Additionally, experimental evidence presented in the enclosed Declaration under 37 C.F.R. § 1.132 of Dr. G. John Stanton demonstrates the colostrinin-induced differentiation of a second cell line, the SH-SY5Y cell line.

Applicant submits that one skilled in the art would conclude from the data in Exhibit A of the Declaration under 37 C.F.R. § 1.132 of G. John Stanton that colostrinin is capable of inducing neuronal cell differentiation in the SH-SY5Y cell line. Applicants respectfully submit that from these results with the SH-SY5Y cell line and the data in the specification showing colostrinin-induced differentiation of the PC-12 cell line, one skilled in the art would conclude that colostrinin promotes neuronal cell differentiation. Thus, Applicants respectfully submit that the specification provides adequate guidance to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention of claims 1-13.

Further, the Examiner alleged that undue experimentation would be required to make and/or use the claimed invention, drawn to "neural cells," which are "any cells derived from the neural crest" (p. 6, Office Action mailed September 10, 2002). Claims 1-13 are drawn to "neuronal cells." It is respectfully submitted that the specification provides adequate guidance to practice the claimed invention with neuronal cells, which are nerve-like cells that morphologically resemble nerve cells. See p. 3, lines 12-18 of the specification. Withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is requested.

Finally, the Examiner alleged that undue experimentation would be required of the skilled artisan to make and/or use the claimed invention for the full scope of "analogs" (see p. 7 of the Office Action mailed September 10, 2002). Claims 1-13 are drawn to active analogs, "wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34." It is respectfully submitted that p. 8, line 14 through p. 10, line 22 of the specification provides adequate guidance for the preparation and use of such active analogs in

the methods of claims 1-13. Withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is requested.

The 35 U.S.C. §112, First Paragraph, Rejection of claims 14 and 15

The Examiner rejected claims 14-15 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The Examiner alleged that "the specification, while being enabling for a method of treating non-functional neural cells comprising contacting non-functional neuronal cells, including those in patients, with a neural cell regulator comprising administering SEQ ID NO:2 or one active analog thereof which is full-length colostrinin, under conditions effective to convert non-functional neuronal cells to functional neuronal cells when the non-function is the result of neurodegeneration, does not reasonably provide enablement [for the treatment of] non-functional cells resulting from damage or trauma" (p. 7 of Office Action mailed September 10, 2002). This is respectfully traversed.

Specifically, the Examiner alleged that the only active analog enabled by the specification is full-length colostrinin (see p. 7 of the Office Action mailed September 10, 2002). Claims 14 and 15 are drawn to active analogs, "wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34." For the reasons discussed in the paragraphs above, it is respectfully submitted that the specification provides adequate guidance for the use of such active analogs in the methods of claims 14 and 15.

Further, the Examiner alleged that the specification does not provide enablement for the treatment of non-functional cells resulting from damage or trauma (see p. 8 of the Office Action mailed September 10, 2002). It is noted that claims 14 and 15 are drawn to a method for treating damaged neuronal cells, wherein the nonfunction is the result of neurodegeneration. It

is submitted that the specification provides adequate guidance for the treatment of nonfunctional neuronal cells, wherein the nonfunction is the result of neurodegeneration (see, for example, p.11, line 20 through p. 14, line 14). Withdrawal of the rejection of claims 14 and 15 under 35 U.S.C. §112, first paragraph, is respectfully requested.

For the reasons discussed above, withdrawal of the rejection of claims 1-15 under 35 U.S.C. §112, first paragraph, is respectfully requested.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 14 and 15 under 35 U.S.C. §102 as being anticipated by Janusz et al. (WO 98/14773). This rejection is respectfully traversed. According to MPEP § 2131 a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Claim 14 is drawn to a method for treating damaged neuronal cells by contacting nonfunctional neuronal cells with a neuronal cell regulator under conditions effective to convert the damaged neuronal cells to functional neuronal cells. Claim 15 is drawn to a method for treating damaged neuronal cells in a patient by administering a neuronal cell regulator under conditions effective to convert damaged neuronal cells to functional neuronal cells. Thus the claimed invention is drawn to the administration of a neuronal cell regulator under conditions effective to convert the damaged neuronal cells to functional neuronal cells.

Janusz et al. teach the treatment of a broad range of disorders, from Parkinson's disease and Alzheimer's disease to psychosis and neurosis. See p. 2, lines 16-22 of Janusz et al. The mechanism of action in the treatment method taught in Janusz et al. is the induction of a state of immune system hyporeactivity or tolerance, manifested by the inability to synthesis IFN and TNF-α. See p. 20, lines 6-9 and p. 21, lines 12-14. This state of immune system hyporeactivity or tolerance is only temporary, reversing once the administration of the colostrinin is stopped. See p. 20, lines 11- 16 and p. 21, lines 17-21. Thus, Janusz et al. does not disclose a method for the treatment of damaged neuronal cells by the administration of a

neuronal cell regulator under conditions effective to convert the damaged neuronal cells to functional neuronal cells.

As discussed above, Janusz et al. do not set forth each and every element of claims 14 and 15. Withdrawal of this rejection under 35 U.S.C. § 102(b) is respectfully requested.

Summary

It is respectfully submitted that the pending claims 1-15 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

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January 7, 2003
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CERTIFICATE UNDER 37 CFR §1.10:
"Express Mail" mailing label number: EV 183606725 US Date of Deposit: January 7, 2003
The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.
By:
Name: Marc Ireland

APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS INCLUDING NOTATIONS TO INDICATE CHANGES MADE
Serial No.: 09/641,802
Docket No.: 265.00240101

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments have been shaded.

In the Title

The title has been amended as follows:

"USE OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF, TO PROMOTE NEURONAL [NEURAL] CELL DIFFERENTIATION."

In the Specification

The paragraph beginning at page 9, line 18, has been amended as follows:

As stated above, active analogs of colostrinin and its constituent peptides include polypeptides having structural similarity. Structural similarity is generally determined by aligning the residues of the two amino acid sequences to optimize the number of identical amino acids along the lengths of their sequences; gaps in either or both sequences are permitted in making the alignment in order to optimize the number of identical amino acids, although the amino acids in each sequence must nonetheless remain in their proper order. Preferably, two amino acid sequences are compared using the Blastp program, version 2.0.9, of the BLAST 2 search algorithm, available [at http://www.ncbi.nlm.nih.gov/gorf.b12.html] on the worldwide web at ncbi.nlm.nih.gov/gorf/b12.html. Preferably, the default values for all BLAST 2 search parameters are used, including matrix = BLOSUM62; open gap penalty = 11, extension gap penalty = 1, gap x_dropoff = 50, expect = 10, wordsize = 3, and filter on. In the comparison of two amino acid sequences using the BLAST search algorithm, structural similarity is referred to as "identity." Preferably, an active analog of colostrinin or its constituent peptides has a structural similarity to colostrinin or one or more of its constituent peptides (preferably, one of SEQ ID NOs:1-34) of at least about 70% identity, more preferably, at least about 80% identity, and most preferably, at least about 90% identity.

The paragraph beginning at page 3, line 9, has been amended as follows:

In other embodiments, the invention provides the use of a neural [nueral] cell regulator in the manufacture of a medicament for use in the methods described herein.

The paragraph beginning at page 8, line 10, has been amended as follows:

The polypeptides of SEQ ID NOs:1-34 can be in their free acid form or they can be amidated at the C-terminal carboxylate group. The present invention also includes analogs of the polypeptides of SEQ ID NOs:1-34, which includes polypeptides having structural similarity with SEQ ID NOs:1-34. These peptides can also form a part of a larger peptide. An "analog" of a polypeptide includes at least a portion of the polypeptide, wherein the portion contains deletions or additions of one or more contiguous or noncontiguous amino acids, or containing one or more amino acid substitutions. An "analog" can thus include additional amino acids at one or both of the termini[terminii] of the polypeptides listed above. Substitutes for an amino acid in the polypeptides of the invention are preferably conservative substitutions, which are selected from other members of the class to which the amino acid belongs. For example, it is well-known in the art of protein biochemistry that an amino acid belonging to a grouping of amino acids having a particular size or characteristic (such as charge, hydrophobicity, and hydrophilicity) can generally be substituted for another amino acid without substantially altering the structure of a polypeptide.

In the Claims

For convenience, all pending claims are shown below.

1. [AMENDED] A method for promoting cell differentiation, the method comprising contacting cells with a [neural] neuronal cell regulator selected from the group of colostrinin, a constituent peptide thereof, an active analog thereof, and combinations thereof, under conditions effective to change the cells in morphology to form [neural] neuronal cells; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline

and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34.

2. The method of claim 1 wherein the cells are present in a cell culture, an organ, a tissue, or an organism.

3. The method of claim 1 wherein the cells are mammalian cells.

4. The method of claim 3 wherein the cells are human cells.

5. The method of claim 1 wherein the cells are pluripotent cells.

6. [AMENDED] The method of claim 1 wherein the [neural] neuronal cell regulator is a constituent peptide of colostrinin.

7. [AMENDED] The method of claim 6 wherein the [neural] neuronal cell regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), VESYVPLFP

(SEQ ID NO:31), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), and combinations thereof.

8. [AMENDED] The method of claim 7 wherein the [neural] neuronal cell regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), and combinations thereof.

9. [AMENDED] A method for promoting [neural] neuronal cell differentiation in a patient, the method comprising administering to the patient a [neural] neuronal cell regulator selected from the group of colostrinin, a constituent peptide thereof, an active analog thereof, and combinations thereof, under conditions effective to promote differentiation of cells to form [neural] neuronal cells; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34.

10. The method of claim 9 wherein the patient is a human.

11. [AMENDED] The method of claim 9 wherein the [neural] neuronal cell regulator is a constituent peptide of colostrinin.

12. [AMENDED] The method of claim 11 wherein the [neural] neuronal cell regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6),

VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), VESYVPLFP (SEQ ID NO:31), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), and combinations thereof.

13. [AMENDED] The method of claim 12 wherein the [neural] neuronal cell regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), and combinations thereof.

14. [AMENDED] A method for treating damaged [neural] neuronal cells, the method comprising contacting nonfunctional [neural] neuronal cells with a [neural] neuronal cell regulator selected from the group of colostrinin, a constituent peptide thereof, an active analog thereof, and combinations thereof, under conditions effective to convert the damaged [neural] neuronal cells to functional [neural] neuronal cells; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34, and wherein the nonfunction is the result of neurodegeneration.

15. [AMENDED] A method for treating damaged [neural] neuronal cells in a patient, the method comprising administering to the patient a [neural] neuronal cell regulator selected from the group of colostrinin, a constituent peptide thereof, an active analog thereof, and combinations thereof, under conditions effective to convert damaged [neural] neuronal cells to functional [neural] neuronal cells; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34 and wherein the nonfunction is the result of neurodegeneration.